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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,668	12/05/2003	Peter M. Bonutti	2500DV2CN2DV3CN2	3159

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,668

Applicant(s)

BONUTTI, PETER M.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 7,9,12,14-19,43-47,53-55,64,65,85-88,95 and 96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10,11,13,20-42,48-52,56-63,66-84,89-94 and 97-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 7, 9, 12, 14-19, 43-47, 53-55, 64, 65, 85-88, 95 and 96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 18, 2004. Contrary to applicant's remarks, claims 12 and 85-88 do not read on the elected species. Claim 12 depends from claim 7 (which is drawn to a nonelected species as admitted by applicant). Claims 85-88 read on the species of figures 12 and 12A rather than the elected species of figures 11 and 11A.

Copies of the Foreign Patents and Other Documents cited in the Information Disclosure Statement filed March 5, 2004 are requested. Contrary to the remarks in the Statement, copies of these documents are not present in Application Serial No. 10/662,923.

The disclosure is objected to because of the following informalities: In claim 58, line 2, "bladders" should be "bladder" for correct grammar. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This application is described as a continuation of one of many parent applications. There is no basis in the parent applications for the limitation that the instrument is introduced through bone. Although the disclosure indicates that the instrument is inserted between bones, it does not indicate that it is inserted through bone.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 60 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 11, line 1, there is no antecedent basis for "the bladder". Claim 60 is

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confusing and inaccurate. Although the bladder is inflated without unconfined fluid present in the joint, the pressure is unconfined since it forces the bones of the joint to separate. In claim 84, line 1, there is no antecedent basis for "the tissue".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 8, 10, 11, 13, 27-30, 38-42, 48-51, 59-62, 66-70, 72 and 73 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon discloses the steps of providing a retractor (e.g. 10, 57, 57a in figure 4) having a distal portion and an expandable body 57 coupled to the distal

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portion, positioning the expandable body between adjacent vertebrae (noting the term "inter-vertebral space" in col. 9, lines 62-66) and expanding the expandable body to spread the adjacent vertebrae apart (The expansion of the expandable body 57 within the inter-vertebral space creates space for viewing as described in col. 9, lines 66-70. The creation of this space between the vertebrae inherently spreads the adjacent vertebrae apart.) Alternatively, it would have been obvious that the creation of this space between the vertebrae spreads the adjacent vertebrae apart since the space that is created is located between the vertebrae. As to claim 8, bladder 57 is wedge-shaped as seen in figure 4. As to claim 49, Sheldon discloses the step of introducing the retractor through a passage of a cannula 5 (col. 3, lines 9-13).

Claims 2-5, 20-26, 31-37, 52, 63, 71, 74, 78-80, 82-84, 89-94 and 97-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745). Sheldon fails to specifically indicate that the herniated disc described from col. 1, line 51 to col. 2, line 7 is operated on. However, it is old and well known in this art to remove an intervertebral disc when it is diagnosed as being herniated in order to obtain the advantage of relieving pain. It would have been obvious to remove the herniated disc during the Sheldon procedure so that

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this procedure too would have this advantage. As to claim 71, Sheldon fails to disclose applying a vacuum to deflate the bladder 57. However, it is old and well known in this art to deflate a balloon by applying a vacuum to the balloon in order to obtain the advantage of quickly deflating it. It would have been obvious to use a vacuum to deflate the Sheldon bladder 57 so that it too would have this advantage.

Claims 56-58, 75-77 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745) in view of McDaniel (4,501,266). Sheldon fails to disclose using the device in a knee. However, Sheldon does teach that the device may be used in areas of the body other than the spine (col. 2, lines 8-9). Further, McDaniel teaches that the knee is an area of the body that requires surgical intervention and distraction. It would have been obvious to use the Sheldon device in the knee for this reason.

Claims 1, 2, 4, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (3,916,907). Peterson discloses the steps of providing a retractor 30 having a distal portion (e.g. pivot 35) and an expandable body (the portions of members 31, 32 which extend distally from pivot 35) coupled to the distal portion, positioning the expandable body between adjacent vertebrae and expanding the expandable body to

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spread the adjacent vertebrae apart (col. 4, lines 41-47). As to claims 2, 4 and 5, Peterson discloses removing the intervertebral disc (col. 4-9).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8, 10, 11, 13, 20-42, 48-52, 56-63, 66-84, 89-94 and 97-101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,017,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor differences between the claims involve merely obvious differences.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

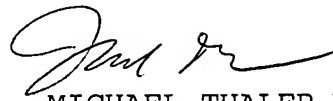
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
11/3/04


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731